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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,465	02/09/2005	Hirofumi Doi	3190-069	7622

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KILYK & BOWERSOX, P.L.L.C.
400 HOLIDAY COURT
SUITE 102
WARRENTON, VA 20186

EXAMINER

SHEN, BIN

ART UNIT PAPER NUMBER

1655

DATE MAILED: 08/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/519,465

Applicant(s)

DOI ET AL.

Examiner

Bin Shen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 20-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-10, 20-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, drawn to an inhibitor of c-Jun phosphorylation.

Group II, claim(s) 2, drawn to a method for inhibiting c-Jun phosphorylation.

Group III, claim(s) 3-4, 21-23, drawn to an agent for preventing and/or treating a disorder.

Group IV, claim(s) 5-6, 24-26, drawn to a method for preventing and/or treating a disorder.

Group V, claim(s) 7, drawn to a method for identifying a compound that inhibiting the binding of p21-activated kinase 4 to MAP kinase kinase 7.

Group VI, claim(s) 8, drawn to a method for identifying a compound that inhibiting the binding of JNK/SAPK inhibitory kinase to MAP kinase kinase 7.

Group VII, claim(s) 9, drawn to a method for identifying a compound that inhibits the phosphorylation of MAP kinase kinase 7 cause by p21-activated kinase 4.

Group VIII, claim(s) 10, drawn to a method for identifying a compound that inhibits the phosphorylation of MAP kinase kinase 7 cause by JNK/SAPK-inhibitory kinase.

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Group IX, claim(s) 20, drawn to a pharmaceutical composition.

Group X, claim(s) 27-28, drawn to an agent kit.

The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the invention groups fail to share a common special technical feature. For example, Group 1 invention inhibitor doesn't have any relationship to any of the method group inventions (e.g. Group II and V) because the inhibitor is not required to perform the methods of identifying a compound. Thus, there is no special technical feature that they all share. Lack of unity exists.

Election of Species

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- A. The type of causes of c-Jun phosphorylation inhibition from among those instantly claimed-i.e., inhibiting the binding of p21-activated kinase 4 (PAK4) to MAP kinase kinase 7 (MKK7); inhibiting the phosphorylation of MKK7 caused by PAK4; etc., -see, e.g., claims 1, 2, 3 and 5.
- B. The type of compound/inhibitor in the pharmaceutical composition from among those instantly claimed- i.e., a compound that inhibits the binding of p21-activated kinase

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4 to MKK7; an inhibitor of the binding of PAK4 to MKK7; etc., -see, e.g., claims 20, 21 and 24.

C. The type of disorders from among those instantly claimed- i.e., polyglutamine disease; Huntington's disease; etc.,- see, e.g., claims 23 and 26.

D. The type of members of the reagent kit from among those instantly claimed- i.e., p21-activated kinase 4; JNK/SAPK-inhibitory kinase; etc.,- see, e.g., claim 27.

Applicant is required, in reply to this action, to elect a single species from each type (i.e., for Group A-elect inhibiting the binding of p21-activated kinase 4, from among those instantly claimed such as recited in claims 1, 2, 3, 5; for Group B-elect a compound that inhibits the binding of p21-activated kinase 4 to MKK7, from among those instantly claimed such as recited in claims 20, 21, 24) to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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The following claim(s) are generic: 1, 2, 3, 5, 20, 21, 24, 27.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the numerous inhibition activities instantly claimed (e.g., inhibiting the binding of p21-activated kinase 4 vs. inhibiting the phosphorylation of MKK7 caused by PAK4, etc.) are different and distinct, each from the other (and, thus, do not share a special technical feature, each with the other); and the various types of disorders (e.g., Huntington's disease, spino-cerebellar ataxia, bulbo-spinal muscular atrophy) are different and distinct, each from the other (and, thus, do not share a special technical feature, each with the other).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

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Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the

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scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Bin Shen, Ph.D., whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey can be reached at (571) 272-0775.

A handwritten signature in black ink, appearing to read 'M. Meller', with a long horizontal flourish extending to the right.

**MICHAEL MELLER
PRIMARY EXAMINER**

B Shen

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